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FILE 70236/001

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NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year)

02.08.2001

Applicant's or agent's file reference
9.70236/001

IMPORTANT NOTIFICATION

International application No.
PCT/GB00/01843

International filing date (day/month/year)
15/05/2000

Priority date (day/month/year)
14/05/1999

Applicant
AFFIBODY TECHNOLOGY SWEDEN AB

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

- The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 9.70236/001	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/01843	International filing date (day/month/year) 15/05/2000	Priority date (day/month/year) 14/05/1999
International Patent Classification (IPC) or national classification and IPC C07K1/22		
Applicant AFFIBODY TECHNOLOGY SWEDEN AB		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 7 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 14/12/2000	Date of completion of this report 02.08.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Döpfer, K-P Telephone No. +49 89 2399 8547 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/01843

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-26 as originally filed

Claims, No.:

1-26 as originally filed

Drawings, sheets:

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

- ☐ the drawings, sheets:
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)
6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
- ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- ☒ all parts.
- ☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims
	No:	Claims 1-26
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-26

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/01843

Industrial applicability (IA) Yes: Claims 1-26
 No: Claims

2. Citations and explanations
 see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item I

Basis of the report

Re Item IV

Lack of unity of invention

1. Self assembled biomolecules with the features of present claim 1 are known from the prior art (see Item V infra). Therefore, no special technical feature characterising the invention and contributing to novelty and inventive step is anymore present (Rule 13(2) PCT). Thus, the present application lacks unity of the invention *a posteriori* (Rule 13(1)(2) PCT). Every novel protein or nucleic acid or any chimeric molecule would represent a separate invention.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:
 - D1: K NORD ET AL.: 'Binding proteins selected from combinatorial libraries of an alpha-helical bacterial receptor domain' NATURE BIOTECHNOLOGY., vol. 15, no. 8, August 1997 (1997-08), pages 772-777, XP002149252 NATURE PUBLISHING., US ISSN: 1087-0156 cited in the application
 - D2: W A PETKA ET AL.: 'Reversible hydrogels from self-assembling artificial proteins ' SCIENCE., vol. 281, 17 June 1998 (1998-06-17), pages 389-392, XP002149253 AAAS. LANCASTER, PRIOR ART., US cited in the application
 - D3: S VOSS & A SKERRA: 'Mutagenesis of a flexible loop in streptavidin leads to higher affinity for the Strep-tag II peptide and improved performance in recombinant protein purification ' PROTEIN ENGINEERING, vol. 10, no. 8, 1997, pages 975-982, XP002149254 ENGLAND GB
 - D4: K NORD ET AL.: 'Ligands selected from combinatorial libraries of protein A for use in affinity capture of apolipoprotein A-1M and Taq DNA polymerase' JOURNAL OF BIOTECHNOLOGY., vol. 80, 2000, pages 45-54,

XP002149255 ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM., NL
ISSN: 0168-1656

D5: E GUNNERIUSSON ET AL.: 'Affinity maturation of a Taq DNA polymerase specific affibody by helix shuffling' PROTEIN ENGINEERING, vol. 12, no. 10, October 1999 (1999-10), pages 873-878, XP002149256 ENGLAND GB

D6: P GROB ET AL.: 'A system for stable indirect immobilization of multimeric recombinant proteins' IMMUNOTECHNOLOGY., vol. 4, no. 2, October 1998 (1998-10), pages 155-163, XP002149257 ELSEVIER SCIENCE PUBLISHERS BV., NL ISSN: 1380-2933 cited in the application

2. The present application relates to self-assembled biomolecular structures comprising affinity modules with at least two affinity domains.

2.1 Novelty and Inventive Step (Article 33(2)(3) PCT)

The following assessment of substantive matters (novelty, inventive step) is established under the provisos made under Item VIII of this Report.

The wording of present claim 1 is so general that its subject-matter cannot be considered novel over the prior art documents D1 to D3 and D6. (Documents D4 and D5 are not forming part of the prior art as stipulated in Rule 64 PCT). Even antibodies or specific nucleic acids would fall under the claim as filed (see also Item VIII of this Report).

Also the subject-matter of dependent claims 2-12 is not novel in view of the disclosure of D1 to D3. D6 in its entirety is anticipating for the novelty of all present claims 1-26.

The combinatorial libraries claimed are not novel either nor are the methods for selecting a molecule using these libraries. These methods are common knowledge of the skilled person in the art.

Nevertheless, the subject-matter covered by the particular examples of the present application appear to be novel and, in view of the prior art cited in the

International search report, involving an inventive step.

2.2 Industrial applicability (Article 33(4) PCT)

The subject-matter of present claims 1-26 appear to comply with the requirements of industrial applicability as stipulated in Article 33(4) PCT.

Re Item VIII

Certain observations on the international application

1. Independent claims 1 and 17 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved which merely amounts to a statement of the underlying problem. The technical features necessary for achieving this result should be added. The claims dependent upon these claims are not clear either.
2. The term "substantially" used in claims 19-21 is vague and unclear and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject-matter of said claims unclear (Article 6 PCT).